Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2200435	10/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
North Eastern Dermatology, Pc Dba	12 East Willow Street, Millburn, NJ	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory reagents and interview with the Testing Personnel (TP), the laboratory failed to ensure protection from chemical and physical hazards at the time of survey. The findings include: 1. Observation of the flammable cabinet and wall mounted cabinets revealed that all flammable and inhalation risk reagents were not kept in the flammable cabinet. 2. One container Select Eosin was in the laboratory wall cabinet. 3. The TP confirmed on 10/12/22 at 1: 35 pm that the laboratory did not ensure protection from chemical and physical hazards.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the lack of Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice a year in the calendar year 2022. The LD confirmed on 10/12/22 at 2:00 pm that BA was not performed.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to have a procedure for microscope maintenance from February 2022 to the date of the survey. The LD confirmed on 10 /12/22 at 2:30 pm that the laboratory failed to have a procedure for microscope maintenance. b) Based on surveyor review of the Procedure Manual (PM), observation of Auto Stainer (AS) and interview with the Testing Personnel (TP), the laboratory failed to follow the PM for Hematoxyilin-Eosin (HE) staining from February 2022 to the date of the survey. The findings include: 1. The AS in the laboratory did not correspond with the staining procedure in the PM. 2. The AS steps in the PM were as follows: Steps 1- XS-3, 2- XS-3, 3- XS-3, 4 - 100% Alcohol, 5 - 100% Alcohol, 6 - 95% Alcohol, 7 - 95% Alcohol, 8 - Running water, 9 - Hematoxylin, 10 - Running water, 11 - Define MX-aq, 12 - Running water, 13 - Blue Buffer 8, 14 - Running water, 15 - 95% Alcohol, 16 - Eosin, 17 - 95% Alcohol, 18 - 95% Alcohol, 19 - 100% Alcohol, 20 - 100% Alcohol, 21 - XS-3, 22 - XS-3, 23 - XS-3. 3. The observation of the staining solutions and reagents in the AS were as follows: Steps 1-XS-3, 2-XS-3, 3-100% Alcohol, 4-100% Alcohol, 5-95% Alcohol, 7- blank, 8-Bluing buffer, 9-Define MX-aq, 10-Hematoxylin, 121-Blank, 12-Eosin, 13-95% Alcohol, 14-95%Alcohol, 15-100% Alcohol, 16-100% Alcohol, 17-XS-3, 18-XS-3. 4. The TP confirmed on 10/12/22 at 2:30 pm that the laboratory did not follow the PM. c) Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to have a procedure for Biannual Assesment (BA) from February 2022 to the date of the survey. The LD confirmed on 10/12/22 at 2:30 pm that the laboratory failed to have a procedure for BA.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of Xylene reagent and interview with the Testing Personnel (TP), the laboratory used expired Xylene reagent on the Tissue Tek VIP tissue processor from 7/28/22 to the date of survey. The findings include: 1. Xylene Lot # 1920418 expired 7/28/22. 2. Approximately 240 patients were tested a month with the expired reagent. 3. The TP confirmed on 10/12/22 at 3:30 pm that the laboratory used expired reagent.
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that the FR included all the required information from February 2022 to the date of survey. The finding include: 1. A review of ten FR revealed that the name and address of the laboratory performing the Techincal Competent for Histopathology special staining was not on FR. 2. The LD confirmed on 10/12/22 at 1:45 pm that FR did not have all the required information.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD) , the LD failed to establish a Competency Assessment (CA) procedure with all the required elements for Testing Personnel from February 2022 to the date of survey. The LD confirmed on 10/12/22 at 1:00 pm that a CA procedure was not established.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the LD failed to specify in writing the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, from

	February 2022 to the date of the survey. The LD confirmed on 10/12/22 at 1:20 pm that the LD failed to specify in writing the responsibilities and duties of the aforementioned staff.